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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,909

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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/563,909	Applicant(s) PIROVANO ET AL.	
	Examiner Bhisma Mehta	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-74 is/are pending in the application.
- 4a) Of the above claim(s) 60-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on February 8 2007 is acknowledged. The traversal is on the ground(s) that the system is only for the infusion of a pharmacological solution into the body of a patient. This is not found persuasive because the method as claimed can be used for the infusion of pharmacological solution by generating a flow of the pharmacological solution by a syringe or an IV bag. It should be noted that the system claims of Group I are clearly drawn to the specifics of the adjusting device and the pumping device while the method claims of Group II are drawn to the specifics of programming the flow and infusion times by a programming device.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 60-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 8 2007.

Information Disclosure Statement

3. Part of the information disclosure statement filed January 10 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be

listed; and all other information or that portion which caused it to be listed. The foreign patent documents, which have been crossed out, have not been considered, as these documents have not been received.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the container arrangement, the command and control device, the solenoid valve comprising a solenoid arranged outside a valve part must be shown or the feature(s) canceled from the claim(s). Also, the command and control device operationally associated with a plurality of solenoid valves and each one of the plurality of solenoid valves being associated with a different elastomeric container must be shown or the feature(s) canceled from the claim(s). Also, the command and control device comprising a microprocessor and the check valve of the inlet portion must be shown or the feature(s) canceled from the claim(s). In addition, the command and control device comprising an interface system and a reading device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 6 and 15. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The abstract of the disclosure is objected to because the abstract contains legal phraseology. Correction is required. See MPEP § 608.01(b).
7. The disclosure is objected to because of the following informalities: In lines 20-23 of page 3, there is appears to be a grammatical error with the phrase "The container in elastomeric material".

Appropriate correction is required.

Claim Objections

8. Claims 38-59 are objected to because of the following informalities:

Claim 38 recites the limitations "said pharmacological solution" in line 3, "said container" in line in 3, "said patient" in line 4, and "said flow" in line 5. Claim 42 recites the limitation "the valve part" in line 2. Claim 44 recites the limitation "said flow" in line 2. Claim 45 recites the limitations "said containing arrangement" in lines 1-2, "said pumping means" in line 2, and "said pharmacological solution" in lines 2-3. Claim 48 recites the limitation "said pharmacological solution" in line 3. Claim 50 recites the limitations "the coupling" in line 2 and "said pharmacological solution" in line 3. Claim 56 recites the limitation "said data recording support" in line 2. Claim 59 recites the limitation "said battery" in line 1. There is insufficient antecedent basis for these limitations in these claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 45-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 45, it is unclear how the containing arrangement/container and the pumping means/device can both comprise an elastomeric container if the pumping device is for generating a flow of the pharmacological solution from the container.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 38-42, 44, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Corbin et al (U.S. Patent No. 3,252,623). Corbin et al disclose an infusion system having a container arrangement (10), a pumping device (14), an adjusting device (24), and a command and control device (45). The adjusting device comprises a valve arrangement in the form of a solenoid valve which is normally closed. The command and control device operates the valve arrangement to command a pulsed actuation of the valve arrangement (see lines 16-26 and lines 51-60 of column

3). The command and control device is provided with an electric supply apparatus which is connected to the command and control device by channel (35).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 43 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al in view of Franetzki et al (U.S. Patent No. 4,270,532). Corbin et al disclose the system substantially as claimed. However, Corbin et al are silent on the specifics of the command and control device comprising a microprocessor, an interface element, or a reading device. Franetzki et al disclose an infusion system having a container, a pumping device, and a command and control device comprising a microprocessor (I). The command and control device also has an interface element for operationally connecting the command and control device to a data processing system (44) and a reading device for receiving a data recording support in the form of a smart-card type (lines 38-52 of column 2 and lines 3-24 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the command and control device of Corbin et al with a microprocessor or an interface element as taught by Franetzki et al as Franetzki et al disclose that it is well known to use a command and control device having a microprocessor or an interface

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element to allow the desired infusion to be pre-programmed and monitored by a physician. To provide the command and control device of Corbin et al with a reading device as taught by Franetzki et al would have also been obvious to one having ordinary skill in the art at the time the invention was made as Franetzki et al disclose that it is well known to use a command and control device having a reading device to allow for the programming data which is already stored on a carrier or card to be easily read by the command and control device.

15. Claims 45-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al in view of Kanai et al (U.S. Patent No. 6,367,502). Corbin et al disclose the system substantially as claimed. However, Corbin et al are silent on the pumping device comprising an elastomeric container. Kanai et al disclose an infusion system having a container arrangement and a pumping device comprising an elastomeric container (11) which is supported on a support element (10) associated with a transparent containing and protection element (2). The containing and protection element has a scale (4). The containing and protection element has an inlet portion (19) with a check valve (13) and a connecting element (17) and an outlet portion (18) which is connected to a first end of a fitting element (30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the pumping device of Corbin et al with the pumping device having an elastomeric container as taught by Kanai et al as both Corbin et al and Kanai et al disclose infusion systems having a pumping device and the pumping device of Kanai et al could be used in the infusion system of Corbin et al as an equivalent way of generating a flow of solution.

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16. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al and Kanai et al as applied to claim 45 above, and further in view of Wunsch (U.S. Patent No. 4,559,036). Corbin et al and Kanai et al disclose the system substantially as claimed. However, Corbin et al and Kanai et al are silent on the command and control device being operationally associated with a plurality of solenoid valves where each valve is associated with a different elastomeric container. Wunsch discloses an infusion system having a plurality of solenoid valves (40, 59) where each valve is associated with a pumping device (16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the infusion system of Corbin et al with a plurality of pumping devices and associated solenoid valves as taught by Wunsch as Wunsch discloses that it is well known to use infusion systems having multiple pumping devices and solenoid valves to generate and control the flow of multiple infusion solutions to be delivered into a patient.

17. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbin et al in view of Crankshaw et al (U.S. Patent No. 4,741,732). Corbin et al disclose the system substantially as claimed. However, Corbin et al are silent on the electrical supply apparatus being a battery means. Crankshaw et al disclose an infusion system with a command and control device (120) having a rechargeable battery (129). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the electrical supply apparatus of Corbin et al with the rechargeable battery as taught by Crankshaw et al as Crankshaw et al teach that it is

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well known to use rechargeable batteries to provide the power needed to operate a command and control device in an infusion system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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